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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/009,570	06/19/2002	Iain Alasdair Donaldson	078883-0139	9774

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EXAMINER	
COLLINS, CYNTHIA E	
ART UNIT	**PAPER NUMBER**
1638	

DATE MAILED: 12/14/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/009,570	DONALDSON ET AL.	
	Examiner	Art Unit	
	Cynthia Collins	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 September 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-26* is/are pending in the application.

4a) Of the above claim(s) *6 and 25* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5,7-24 and 26* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *19 June 2002* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *12/01, 1/03*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group I, claims 1-5, 7-24 and 26, in the reply filed on September 27, 2004 is acknowledged. The traversal is on the ground(s) that the claims of Groups I, II and III are sufficiently related to be examined integrally, and that such examination would not place an undue burden on the Examiner.

This is not found persuasive because the searches for Groups I, II and III are not coextensive. The search of Group I requires a search for a specific nucleotide sequence of SEQ ID NO:1, which search is not required for Groups II and III. The search of Group II requires a search for any and all promoters of unspecified sequence obtained from any and all species of the genus Oryza that cause endosperm specific expression, which search is not required for Groups I and III. The search of Group II requires a search for a specific nucleotide sequence of SEQ ID NO:2, which search is not required for Groups I and II.

The requirement is still deemed proper and is therefore made FINAL.

Claims 6 and 25 are withdrawn from consideration as being directed to nonelected inventions.

Claim Objections

Claims 7, 9, 14, 20, 21 and 22 are objected to because of the following informalities: the claims recite the acronyms "NOI" and "POI" without recitation of what the acronyms designate Appropriate correction is required.

Claims 10, 11 and 12 are objected to because of the following informalities: the claims do not comply with the sequence rules set forth in 37 CFR 1.821 - 1.825. Specifically, claims 10, 11 and 12 fail to comply with 37 CFR 1.821(d), in that reference is not made to the sequences presented in Table 1 by use of a sequence identifier preceded by "SEQ ID NO:" in the text of the claims. Appropriate correction is required.

Information Disclosure Statement

Initialed and dated copies of Applicant's IDS forms 1449, filed January 9, 2003 and December 12, 2001 are attached to the instant Office action.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-2, 5, 7-22 and 26 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to a promoter comprising or having a nucleotide sequence corresponding to that shown as SEQ ID No. 1 or a variant, homologue, fragment or derivative thereof, including a promoter that is obtainable from a plant of the genus Oryza. The claims are

also drawn to a promoter according to claim 1 that is linked to the sequence presented as SEQ ID No. 2, or a variant, homologue, derivative or fragment thereof, including a promoter wherein if an NO1 is operably linked thereto then the sequence presented as SEQ ID No. 2, or a variant, homologue, derivative or fragment thereof is located intermediate the promoter and the NOI. The claims are additionally drawn to a promoter according to claim 1 wherein the promoter comprises one or more of the identified sequences presented in Table 1 or a variant, homologue or fragment thereof. The claims are further drawn to a promoter according to claim 1 that is linked to the sequence presented as SEQ ID No. 5 or a variant, homologue, derivative or fragment thereof, including a promoter wherein if an NO1 is operably linked thereto then the sequence presented as SEQ ID No. 5, or a variant, homologue, derivative or fragment thereof is located intermediate the promoter and the NOI.

The specification describes an isolated promoter polynucleotide obtained from the rice sucrose synthase 3 gene, said promoter comprising and having a 1772 bp nucleotide sequence corresponding to that shown as SEQ ID No. 1 (page 94; sequence listing). The specification also describes twelve different truncations of SEQ ID NO:1 that function to express a GUS reporter gene in guar endosperm (pages 96-101; Figures 13-18). The specification additionally describes an intron polynucleotide comprising a 865 bp nucleotide sequence corresponding to that shown as SEQ ID No. 2, and an exon polynucleotide comprising a 31 bp nucleotide sequence corresponding to that shown as SEQ ID No. 5 (sequence listing).

The specification at page 16 additionally discloses that the terms "variant" and "homologue" are synonymous with allelic variations of the nucleotide sequence of the present invention, the specification at page 20 further discloses that the terms "variant", "homologue",

"fragment" and derivative" embrace allelic variations of the disclosed sequences, and that the term "variant" also encompasses sequences that are complementary to sequences that are capable of hybridizing to the nucleotide sequences presented herein, and the specification at page 26 discloses that the terms "variant,", "homologue" or "fragment" include any substitution of, variation of, modification of, replacement of, deletion of or addition of one (or more) nucleic acid from or to the sequence of the present invention.

The specification does not describe variants, homologues, or derivatives of SEQ ID NO:1, functional fragments of SEQ ID NO:1 other than the twelve different truncations disclosed, or promoter sequences other than SEQ ID NO:1 that were obtained from a plant of the genus Oryza. The specification does not describe variants, homologues, fragments or derivatives of SEQ ID NO:2, or a promoter according to claim 1 that is linked to the sequence presented as SEQ ID No. 2. The specification does not describe promoters that comprise one or more of the identified sequences presented in Table 1, or variants, homologues or fragments of the identified sequences presented in Table 1. The specification does not describe variants, homologues, fragments or derivatives of SEQ ID NO:5, or a promoter according to claim 1 that is linked to the sequence presented as SEQ ID No. 5.

The Federal Circuit has recently clarified the application of the written description requirement to nucleotide sequences. The court stated that "A description of a genus of cDNAs may be achieved by means of recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to members of the genus, which features constitute a substantial portion of the genus."

See *University of California v. Eli Lilly and Co.*, 119 F.3d 1559, 1569; 43 USPQ2d 1398, 1406 (Fed. Cir. 1997).

In the instant case Applicant has not described a representative number of species falling within the scope of the claimed genus which encompasses numerous different promoter sequences comprising undisclosed variants, homologues, fragments and/or derivatives of SEQ ID NOS:1, 2 and 5 and the identified sequences presented in Table 1, nor the structural features unique to the genus.

Claim 23 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claim 23 is drawn to a promoter sequence obtainable from Deposit No. NCIMB 41011.

Since the plasmid deposited as NCIMB 41011 is essential to the claimed invention, it must be obtainable by a repeatable method set forth in the specification or otherwise be readily available to the public. If the plasmid is not so obtainable or available, the requirements of 35 U.S.C. 112 may be satisfied by a deposit thereof. The specification does not disclose a repeatable process to obtain the exact same plasmid in each occurrence and it is not apparent if such a plasmid is readily available to the public. If the deposit of this plasmid has been made under the terms of the Budapest Treaty, then an affidavit or declaration by the applicants, or a statement by an attorney of record over his or her signature and registration number, stating that

the plasmid will be irrevocably and without restriction or condition released to the public upon the issuance of a patent would satisfy the deposit requirement made herein.

If the deposit has not been made under the Budapest Treaty, then in order to certify that the deposit meets the criteria set forth in 37 CFR 1.801-1.809, applicants may provide assurance of compliance by an affidavit or declaration, or by a statement by an attorney of record over his or her signature and registration number showing that

(a) during the pendency of the application, access to the invention will be afforded to the Commissioner upon request;

(b) all restrictions upon availability to the public will be irrevocably removed upon granting of the patent;

(c) the deposit will be maintained in a public depository for a period of 30 years or 5 years after the last request or for the enforceable life of the patent, whichever is longer;

(d) the viability of the biological material at the time of deposit will be tested (see 37 CFR 1.807); and

(e) the deposit will be replaced if it should ever become inviable.

For each deposit made pursuant to these regulations, the specification shall be amended to contain (see 37 CFR § 1.809):

(1) The accession number for the deposit;

(2) The date of the deposit;

(3) A description of the deposited biological material sufficient to specifically identify it and to permit examination; and

(4) The name and address of the depository.

Claims 1-2, 5, 7-22 and 26 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a promoter comprising or having a nucleotide sequence corresponding to that shown as SEQ ID No. 1 and the disclosed functional fragments of SEQ ID NO:1, does not reasonably provide enablement for undisclosed variants, homologues, fragments or derivatives of SEQ ID NO:1, or for other promoters obtained from other plant species of the genus Oryza, or for a promoter according to claim 1 that is linked to the sequence presented as SEQ ID No. 2, or a variant, homologue, derivative or fragment thereof, or for a promoter according to claim 1 wherein the promoter comprises one or more of the identified sequences presented in Table 1 or a variant, homologue or fragment thereof, or for a promoter according to claim 1 that is linked to the sequence presented as SEQ ID No. 5 or a variant, homologue, derivative or fragment thereof. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The claims are drawn to a promoter comprising or having a nucleotide sequence corresponding to that shown as SEQ ID No. 1 or a variant, homologue, fragment or derivative thereof, including a promoter that is obtainable from a plant of the genus Oryza. The claims are also drawn to a promoter according to claim 1 that is linked to the sequence presented as SEQ ID No. 2, or a variant, homologue, derivative or fragment thereof, including a promoter wherein if an NO1 is operably linked thereto then the sequence presented as SEQ ID No. 2, or a variant, homologue, derivative or fragment thereof is located intermediate the promoter and the NOI. The claims are additionally drawn to a promoter according to claim 1 wherein the promoter comprises one or more of the identified sequences presented in Table 1 or a variant, homologue

or fragment thereof. The claims are further drawn to a promoter according to claim 1 that is linked to the sequence presented as SEQ ID No. 5 or a variant, homologue, derivative or fragment thereof, including a promoter wherein if an NO1 is operably linked thereto then the sequence presented as SEQ ID No. 5, or a variant, homologue, derivative or fragment thereof is located intermediate the promoter and the NOI.

The specification discloses the isolation of a promoter polynucleotide from the rice sucrose synthase 3 gene, said promoter comprising and having a 1772 bp nucleotide sequence corresponding to that shown as SEQ ID No. 1 (page 94; sequence listing). The specification also discloses how to make and use twelve different truncations of SEQ ID NO:1 that function to express a GUS reporter gene in guar endosperm (pages 96-101; Figures 13-18). The specification additionally discloses an intron polynucleotide comprising a 865 bp nucleotide sequence corresponding to that shown as SEQ ID No. 2, and an exon polynucleotide comprising a 31 bp nucleotide sequence corresponding to that shown as SEQ ID No. 5 (sequence listing).

The specification at page 16 additionally discloses that the terms "variant" and "homologue" are synonymous with allelic variations of the nucleotide sequence of the present invention, the specification at page 20 further discloses that the terms "variant", "homologue", "fragment" and derivative" embrace allelic variations of the disclosed sequences, and that the term "variant" also encompasses sequences that are complementary to sequences that are capable of hybridizing to the nucleotide sequences presented herein, and the specification at page 26 discloses that the terms "variant,", "homologue" or "fragment" include any substitution of, variation of, modification of, replacement of, deletion of or addition of one (or more) nucleic acid from or to the sequence of the present invention.

The specification does not disclose how to make and use variants, homologues, or derivatives of SEQ ID NO:1, functional fragments of SEQ ID NO:1 other than the twelve different truncations disclosed, or promoter sequences other than SEQ ID NO:1 that were obtained from a plant of the genus Oryza. The specification also does not disclose how to make and use variants, homologues, fragments or derivatives of SEQ ID NO:2, or a promoter according to claim 1 that is linked to the sequence presented as SEQ ID No. 2. The specification additionally does not disclose how to make and use promoters that comprise one or more of the identified sequences presented in Table 1, or variants, homologues or fragments of the identified sequences presented in Table 1. The specification further does not disclose how to make and use variants, homologues, fragments or derivatives of SEQ ID NO:5, or a promoter according to claim 1 that is linked to the sequence presented as SEQ ID No. 5.

The full scope of the claimed invention is not enabled because it is unpredictable whether variants, homologues, fragments or derivatives of SEQ ID NO:1 would function as a promoter, or as an endosperm-preferred promoter, because basal and tissue-specific promoter function requires the presence of specific nucleotides and nucleotide sequence motifs in the promoter polynucleotide, which nucleotides and motifs may not be present in variants, homologues, fragments or derivatives of SEQ ID NO:1. It is likewise unpredictable whether variants, homologues, fragments or derivatives of SEQ ID NO:2 or 5 or the identified sequences presented in Table 1 would retain the functional characteristics of their reference sequences because their function requires the presence of specific nucleotides and nucleotide sequence motifs which nucleotides and motifs may not be present in variants, homologues, fragments or derivatives thereof.

Variants, homologues, fragments or derivatives may lack key nucleotides required for basal promoter function. See, for example, Kim Y et al. (A 20 nucleotide upstream element is essential for the nopaline synthase (nos) promoter activity. Plant Mol Biol. 1994 Jan;24(1):105-17), who teach that various point mutations in the nos promoter can alter the level of promoter activity in tobacco. Mutation of one or more key nucleotides in either of two hexamer motifs or in the octamer spacer region between them significantly altered the level of *nos* promoter activity (Table 2, page 109). A single point mutation in the sixth nucleotide of the hexamer motif resulted in a four to ten fold decrease in promoter activity, whereas a double point mutation in the fourth and fifth nucleotide of the hexamer motif resulted in a two-fold increase in promoter activity. Two independent triple point mutations in the third, fourth and fifth, and sixth, seventh and eighth nucleotides of the octamer spacer region eliminated detectable promoter activity.

Variants, homologues, fragments or derivatives may also lack key nucleotides required for tissue-specific promoter function. See, for example, de Pater S et al. (A 22-bp fragment of the pea lectin promoter containing essential TGAC-like motifs confers seed-specific gene expression.Plant Cell. 1993 Aug;5(8):877-86), who teach that a 22 bp region located from nucleotide -56 to nucleotide -35 of the pea lectin promoter sequence contains three overlapping TGAC-like motifs that function to confer seed-specific gene expression to the promoter (page 877 abstract; page 879 Figure 2).

The full scope of the claimed invention is also not enabled because it is unpredictable whether the promoter of SEQ ID NO:1 would retain its functional characteristics when combined with SEQ ID NOS: 2 or 5 or the identified sequences presented in Table 1, or when combined with their variants, homologues, fragments or derivatives, would function as a promoter, or as an

endosperm-preferred promoter, because the functional characteristics of SEQ ID NO:1 could be negatively affected by the presence of additional specific nucleotides and nucleotide sequence motifs in the promoter sequence.

SEQ ID NOS: 2 or 5 or their variants, homologues, fragments or derivatives may comprise nucleotides or motifs that interfere with the function of SEQ ID NO:1. See, for example, Dolferus R. et al. (Differential interactions of promoter elements in stress responses of the Arabidopsis Adh gene. Plant Physiol. 1994 Aug;105(4):1075-87), who teach that the deletion of region I (-964 to -510) of the Arabidopsis Adh gene promoter results in increased reporter gene expression under uninduced and all stress conditions, suggesting that this promoter region contains binding site for a repressor protein (page 1075 abstract; paragraph spanning pages 1079-1080; Figure 4, A and B; Table I).

The full scope of the claimed invention is additionally not enabled because it is unpredictable whether variants, homologues, fragments or derivatives of SEQ ID NOs:1, 2 or 5 or the identified sequences presented in Table 1 can be obtained from plant species other than rice, because promoter regions may vary between similar genes in the same or other species, and because not all genes are present as homologues in multiple species.

Plant species other than rice may not comprise genes whose promoters comprise variants, homologues, fragments or derivatives of SEQ ID NO:1. See, for example, Huang J. et al. (Complete structures of three rice sucrose synthase isogenes and differential regulation of their expressions. Biosci Biotechnol Biochem. 1996 Feb;60(2):233-9, Applicant's IDS), who teach that the rice sucrose synthase gene, the gene from which SEQ ID NO:1 was obtained, has not

been detected in plant species other than rice (page 233 abstract; page 233 column 2 second paragraph).

In the instant case Applicant has not provided sufficient guidance with respect to the identity and location of key nucleotides and regulatory regions required for basal or tissue-specific promoter function that would be retained by variants, homologues, fragments or derivatives, or plant species other than rice that comprise genes whose promoters comprise variants, homologues, fragments or derivatives. Absent such guidance it would require undue experimentation for one skilled in the art to make and use variants, homologues, fragments or derivatives, as one skilled in the art would have to isolated from undisclosed sources and/or synthesize variant, homologue, fragment or derivative nucleic acid sequences, and then test each sequence and/or sequence combination for basal and endosperm-preferred promoter function in order to discriminate between operative and nonoperative sequences encompassed by the claims.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 5 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 5 is indefinite in the recitation of "obtainable from". It is unclear whether the claims requires that the promoter be obtained from a plant of the genus *Oryza*. It is suggested that the claim be amended to replace "obtainable" with "obtained" in order to overcome the rejection.

Claims 9 and 14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 9 and 14 are indefinite in the recitation of "the promoter of the present invention". There is insufficient antecedent basis for this limitation in claims 13, 8 and 1 from which claims 9 and 14 depend.

Claim 15 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 15 is indefinite in the recitation of "but wherein". It is unclear whether the claims requires that the promoter be operably linked to a NOI. It is suggested that the claim be amended to delete "but" in order to overcome the rejection.

Claims 16, 17 and 18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 16, 17 and 18 are indefinite in the recitation of "the invention according to claim 1". There is insufficient antecedent basis for this limitation in claim 1 from which claims 16, 17 and 18 depend.

Claim 20 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. Claim 20 requires "expressing an NOI", but the claim recites no actual method steps by which this may be accomplished. Claim 20 also optionally requires "isolating the expression

product of the NOI", but the claim recites no actual method steps by which this may be accomplished. Claim 20 additionally optionally requires "isolating the POI", but the claim recites no actual method steps by which this may be accomplished. Claim 20 further does not result in the preparation of a POI as recited in the preamble of the claim.

Claim 22 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. Claim 22 requires "expressing the NOI", but the claim recites no actual method steps by which this may be accomplished. Claim 22 further does not result in the expression of an NOI in endosperm as recited in the preamble of the claim.

Claim 23 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 23 is indefinite in the recitation of "obtainable from". It is unclear whether the claims requires that the promoter sequence be obtained from Deposit No. NCIMB 41011. It is suggested that the claim be amended to replace "obtainable" with "obtained" in order to overcome the rejection.

Claim 26 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 26 is indefinite in the recitation of "substantially as described herein". It is unclear in what way the promoter is substantially the same as a promoter described herein- the

same in terms of structure? the same in terms of function? the same in terms of source material? It is also unclear the degree to which the claimed promoter is the same as a promoter described herein, since those in the art would variably define the amount "substantially".

Claim 26 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 26 is indefinite in the recitation of "with reference to claim 1". It is unclear in what way claim 1 should serve as a basis for reference - is the basis for reference structure? Function? Source material?

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-14, 23 and 26 are rejected under 35 USC 101 because the claimed invention is directed to non-statutory subject matter.

Claims 1-14, 23 and 26 as written do not sufficiently distinguish over nucleic acids as they exist naturally because the claims do not particularly point out any non-naturally occurring products. In the absence of the hand of man, the naturally occurring products are considered non-statutory subject matter. See Diamond v. Chakrabarty, 447 U.S. 303, 206 USPQ 193 (1980). The claims should be amended to indicate the hand of the inventor, e.g., by insertion of "Isolated" or "Purified". See MPEP 2105.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-2, 5, 7, 15-19 and 26 are rejected under 35 U.S.C. 102(b) as being anticipated by Wing et al. (CUGI Rice BAC Library Oryza sativa (japonica cultivar-group) genomic clone nbxb0027L15f, genomic survey sequence, November 3, 1998, GenEMBL Accession No. AQ272200, and A BAC End Sequencing Framework to Sequence the Rice Genome, Database EMGSS3 'Online! , 1998, EMBL Heidelberg, Germany (Abstract), Applicant's IDS filed December 12, 2001, reference A4).

Claims 1-2, 5, 7 and 15-19 are drawn to a promoter comprising or having a nucleotide sequence corresponding to that shown as SEQ ID No. 1 or a variant, homologue, fragment or derivative thereof, including a promoter that is obtainable from a plant of the genus Oryza. The claims are also drawn to a construct, an expression vector, a transformation vector, a transformed host or host cell, including a plant or a plant cell, each of which comprises the claimed promoter. Claim 26 is drawn to a promoter substantially as described herein and with reference to claim 1.

The nucleotide sequence taught by Wing et al. comprises and has nucleotides 29 to 58 of SEQ ID NO:1. The nucleotide sequence taught by Wing et al. is presumed to be a promoter because it has sequence motifs (TATA and CAAT) that are known to be correlated basal promoter function.

Claim 24 is rejected under 35 U.S.C. 102(b) as being anticipated by Invitrogen Catalogue 1997 ("Original TA Cloning Kits, pCR2.1 vector", page 7, Applicant's IDS filed December 12, 2001 reference A5).

Claim 24 is drawn to any one of the plasmids presented in the Experimental Section provided herein.

Invitrogen Catalogue 1997 teaches the plasmid pCR2.1-TOPO (Invitogen), presented at page 65 in the Experimental Section provided herein.

Remarks

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cynthia Collins whose telephone number is (571) 272-0794. The examiner can normally be reached on Monday-Friday 8:45 AM -5:15 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on (571) 272-0804. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Cynthia Collins
Examiner
Art Unit 1638

CC

Cynthia Collins 12/07/04